

10-03-03

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
 51271/35.1

In Re Application Of: Couto et al.

Serial No.

10/632,645

Filing Date

August 1, 2003

Examiner

Not Yet Assigned

Group Art Unit

Not Yet Assigned

Title: **ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR EXPRESSION OF FACTOR VIII**

Address to:

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

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ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR EXPRESSION OF FACTOR VIII**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. _____ as described below.
- ☐ Charge the amount of _____
- ☐ Credit any overpayment.
- ☒ Charge any additional fee required.

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*This certificate may only be used if paying by deposit account.

Mara Featherstone
Signature

Dated: Oct. 2, 2003

Mara K. Featherstone

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CUSTOMER NO. 35735

CC:

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **Coulton et al.**

Docket No.

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Invention: **ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR EXPRESSION OF FACTOR VIII**

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Information Disclosure Statement (including the items listed below)

(Identify type of correspondence)

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Mara Featherstone

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PTO-Form 1449 listing two-hundred ten (210) references (12 pgs.)
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Express Mail Label No. ER393062710US

PATENT APPLICATION
Docket No.: 51271/35.1 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
 Couto et al.)
)
 Serial No.: 10/632,645) Art Unit
)
 Filed: August 1, 2003)
)
 For: ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR)
)
)
)
 Examiner: Not Yet Assigned)

INFORMATION DISCLOSURE STATEMENT

TO THE COMMISSIONER FOR PATENTS:


1. Pursuant to the duty of disclosure, documents listed on the accompanying Form PTO-1449 (or equivalent) are presented for the Examiner's consideration.

- ☒ Copies of listed documents are enclosed. (37 CFR § 1.98(a))
- ☐ Copies of listed U.S. patent documents are omitted because this application was filed after June 30, 2003 and is, thus, subject to image file wrapper processing. Copies of listed foreign patent documents and non-patent literature are enclosed.
- ☒ Copies of the 210 documents listed on the attached Form PTO-1449 on sheets 1-12 are omitted because (1) they are already of record in previous U.S. patent Applications No. 09/740,211, filed December 18, 2000, which is a continuation of Application No. 09/470,618, filed December 22, 1999, on which this application relies for an earlier filing date under 35 U.S.C. § 120; and (2) any information disclosure statement filed in the prosecution of the above-identified Applications comply with 37 CFR §§ 1.98(a) through (c) (37 C.F.R. § 1.98(d)). The references at the bottom of page 12 of the attached Form PTO-1449 can be found in Application No. 09/470,618, filed December 22, 1999, and the references on pages 1 through the top of page 12 of the Form can be found in the file of Application No. 09/364,862, filed July 30, 1999.

2. ☐ The Examiner's attention is directed to the enclosed copy of copending U.S. Patent Application No. _____, filed _____, for _____, which is cited in this application.
3. This information disclosure statement is being submitted (check box a., b., or c.):
- a. ☒ Within three months of the filing date of a national application or entry of the national stage in an international application; or before the mailing of a first Office action on the merits; or before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114. (No statement under 37 CFR 1.97(e) is required.); or
- b. ☐ After the period set forth in paragraph 3a, but before the mailing date of either a final action, a notice of allowance, or an action that otherwise closes prosecution in the application. (Check box i. or ii.)
- i. ☐ A \$180.00 information disclosure statement submission fee set forth in 37 CFR 1.17(p) is enclosed, or
- ii. ☐ A statement specified by 37 CFR 1.97(e) is set forth below; or
- c. ☐ After the mailing date of a final action or notice of allowance and on or before payment of the issue fee. A statement specified by 37 CFR 1.97(e) is set forth below. Enclosed is a \$180.00 information disclosure statement processing fee set forth in 37 CFR 1.17(p).
4. If a statement specified by 37 CFR 1.97(e) is required, the attorney or agent signing below hereby states that:
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement.

5. ☐ A concise explanation of the relevance of each document not in the English language and/or selected documents in the English language is set forth below.

Respectfully submitted,

By 
Mara K. Featherstone
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CUSTOMER NO. 35735

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
51271/35.1 USAPPLICATION NO.
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INFORMATION DISCLOSURE CITATION

Title: **ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR
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APPLICANT – Couto, et al.

FILING DATE-
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,757,006	Jul, 12, 1988	Toole, Jr. et al.			Oct. 28, 1983
	2	4,886,876	Dec. 12, 1989	Zimmerman et al.			Apr. 13, 1987
	3	5,004,803	Apr. 2, 1991	Kaufman et al.			Nov. 14, 1988
	4	5,045,455	Sept. 3, 1991	Kuo et al.			June 14, 1990
	5	5,112,950	May 12, 1992	Meulien et al.			June 26, 1991
	6	5,139,941	Aug. 18, 1992	Muzyczka et al.			Oct. 25, 1991
	7	5,149,637	Sept. 22, 1992	Scandella et al.			Sept. 20, 1990
	8	5,171,844	Dec. 15, 1992	Van Ooyen et al.			June 10, 1988
	9	5,173,414	Dec. 22, 1992	Lebkowski et al.			Oct. 30, 1990
	10	5,422,260	June 6, 1995	Kaufman et al.			May 15, 1992
	11	5,451,521	Sept. 19, 1995	Kaufman et al.			Dec. 9, 1986
	12	5,595,886	Jan. 21, 1997	Chapman et al.			Dec. 3, 1993
	13	5,563,045	Oct. 8, 1996	Pitman et al.			Sept. 14, 1993
	14	5,587,310	Dec. 24, 1996	Kane et al.			July 11, 1994
	15	5,622,856	Apr. 22, 1997	Natsoulis			Aug. 3, 1995
	16	5,633,150	May 27, 1997	Wood et al.			Oct. 9, 1990

EXAMINER

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	17	5,661,008	Aug. 26, 1997	Almstedt et al.			June 5, 1995
	18	5,668,108	Sep. 16, 1997	Capon et al.			May 23, 1995
	19	5,681,746	Oct. 28, 1997	Bodner et al.			Dec. 30, 1994
	20	5,693,499	Dec. 2, 1997	Yonemura et al.			July 18, 1994
	21	5,720,720	Feb. 24, 1998	Laske et al.			March 15, 1996
	22	5,789,203	Aug. 4, 1998	Chapman et al.			June 27, 1994
	23	5,858,351	Jan. 12, 1999	Podsakoff et al.			Jan. 18, 1996
	24	5,846,528	Dec. 8, 1998	Podsakoff et al.			Jan. 16, 1997

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICA- TION DATE	COUNTRY / PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	25	WO 87/07144	Dec. 3, 1987	PCT				
	26	WO 91/07490	May 30, 1991	PCT				
	27	WO 91//09122	June 27, 1991	PCT				
	28	WO 92/01070	Jan. 23, 1992	PCT				
	29	WO 92/08981	May 29, 1992	PCT				
	30	WO 92/16557	Oct. 1, 1992	PCT				
	31	WO 93/03367	Feb. 18, 1993	PCT				
	32	WO 93/03769	Mar. 4, 1993	PCT				

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							YES	NO
	33	WO 94/11503	May 26, 1994	PCT				
	34	WO 96/21035	July 11, 1996	PCT				
	35	WO 97/03195	Jan. 30, 1997	PCT				
	36	EP O 160 457	Jan. 16, 1991	EP				
	37	EP 0 162 067	July 15, 1992	EP				
	38	EP 0 182 448	May 28, 1986	EP				
	39	EP 0 220 618	Oct. 16, 1986	EP				
	40	EP 0 232 112	Dec. 1, 1993	EP				
	41	EP 0 500 734	Feb. 11, 1998	EP				
	42	EP 0 506 757	Aug. 26, 1998	EP				
	43	EP 0 533 862	Oct. 27, 1999	EP				
	44	EP 0 670 332	Sept. 6, 1995	EP				
	45	EP 0 672 138	Sept. 20, 1995	EP				
	46	EP 0 786 474	July 30, 1997	EP				
	47	EP 0 795 021	Sept. 17, 1997	EP				
	48	EP 0 847 057	Oct. 28, 1998	EP				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication, etc.)

49	Aiello et al., "Adenovirus 5 DNA Sequences Present and RNA Sequences Transcribed in Transformed Human Embryo Kidney Cells (KEY-Ad-5 or 293) <i>Virol</i> , 94:460-469 (1979);
50	Antonarakis et al., "Molecular Genetics of Hemophilia A in Man (Factor VIII Deficiency)," <i>Mol Biol. Med.</i> , 4:81-94 (1987);

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51	Berns, "Parvoviridae and Their Replication," in Fields and Knipes (eds.), <i>Fundamental Virology</i> , 2 nd Ed., pp. 817-837 (1991);
52	Boshart et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> 41:521-530 (1985);
53	Buller et al., "Herpes Simplex Virus Types 1 and 2 Completely Help Adenovirus-Associated Virus Replication," <i>J. Virol.</i> , 40:241-247 (1981);
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56	Carter, "Adeno-associated virus vectors," <i>Curr. Opin. Biol.</i> , 3:533-539 (1992);
57	Chu et al., "SV40 DNA transfection of cells in suspension; analysis of the efficiency of transcription and translation of T-antigen," <i>Gene</i> 13:197-202 (1981);
58	Costa and Grayson, "Site-directed mutagenesis of hepatocyte nuclear factor (HNF) binding sites in the mouse transthyretin (TTR) promoter reveal synergistic interactions with its enhancer region," <i>Nucl. Acids, Res.</i> , 19:4139-4145 (1991)
59	Costa et al., "Transcriptional Control of the Mouse Prealbumin (Transthyretin) Gene: Both Promoter Sequences and a Distinct Enhancer Are Cell Specific," <i>Mol. Cell. Biol.</i> , 6:4697 (1986)
60	Davis et al., <i>Basic Methods in Molecular Biology</i> , Elsevier (1986) (Title and Copyright Pages Only);
61	Dijkema et al. "Cloning and Expression of the chromosomal immune interferon gene of the rat," <i>EMBO J.</i> 4:761-767 (1985);
62	Edge, "Total Synthesis of a Human Leukocyte Interferon Gene," <i>Nature</i> 292:756-761 (1981);
63	Felgner et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc Natl. Acad. Sci U.S.A.</i> 84: 7413-7417 (1987);
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65	Glover et al. (ed.), <i>DNA Cloning: A Practical Approach</i> , Vols. I and II, Oxford; New York: IRL Press (1995) (Title and Copyright Pages Only)
66	Gorman et al., "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," <i>Prod. Natl. Acad. Sci USA</i> 79: 6777-6781 (1982);
67	Graham and Van der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," <i>Virol.</i> , 52: 456-467 (1973);
68	Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," <i>J. Gen. Virol.</i> , 36:59-72 (1977);
69	Herzog, et al., "Long-term correction of canine hemophilia B by gene transfer of blood coagulation factor IV mediated by adeno-associated viral vector," <i>Nature Med.</i> , 5:56-63 (1999);
70	Janik et al., "Locations of adenovirus genes required for the replication of adenovirus-associated virus," <i>Proc. Natl. Acad. Sci. USA</i> 78:1925-1929 (1981);

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71	Jay et al., "Chemical Synthesis of a Biologically Active Gene for Human Immune Interferon- γ ," <i>J Biol. Chem.</i> 259:6311-6317 (1984);
72	Kaufman et al., "Synthesis, Processing and Secretion of Recombinant Human Factor VII Expressed in Mammalian Cells," <i>J. Biol. Chem.</i> , 263:6352-6362 (1988);
73	Kaufman, "Biological Regulation of Factor VIII Activity," <i>Ann. Rev. Med.</i> , 43:325-339 (1992);
74	Kim et al., "Use of the human elongation factor 1 α promoter as a versatile and efficient expression system," <i>Gene</i> 91:217-223 (1990);
75	Klein et al., "High-velocity microprojectives for delivering nucleic acids into living cells," <i>Nature</i> 327:70-73 (1987);
76	Kotin, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <i>Hum. Gen. Ther.</i> , 5:793-801 (1994);
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78	Lind et al., "Novel forms of B-domain-deleted recombinant factor VIII molecules; construction and biochemical characterization," <i>Eur. J. Biochem.</i> , 232:19-27 (1995);
79	Maniatis et al., "Regulation of Inducible and Tissue-Specific Gene Expression," <i>Science</i> 236: 1237-1244 (1987);
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81	Matsushita et al., "Adeno-associated virus vectors can be efficiently produced without helper virus," <i>Gene Ther.</i> , 5:938-945 (1998);
82	Mccarty et al., "Sequence Required for Coordinate Induction of Adeno-Associated Virus p.19 and p.40 Promoters by Rep Protein," <i>J. Virol.</i> , 65:2936-2945 (1991);
83	McPherson et al., "Human Cytomegalovirus Completely Helps Adeno-Associated Virus Replication," <i>Virol.</i> 147:217-222 (1985);
84	Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," <i>Nucl. Acids. Res.</i> 18:5322 (1990);
85	Muzyczka, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <i>Curr. Top. Microbiol. Immunol.</i> , 158:97-129 (1992);
86	Naki et al., <i>Blood</i> 91:1-9 (1998); Reference could not be obtained at this time. Will provide a copy at a later date should the Examiner desire a copy.
87	Nambair et al., "Total Synthesis and Cloning of a Gene Coding for the Ribonuclease S Protein," <i>Science</i> 223: 1299-1301 (1984);
88	<i>Remington's Pharmaceutical Sciences</i> 18 th ed., Easton, Pa; Mack Pub. Co. (1990); Reference could not be obtained at this time. Will provide a copy of the Title and copyright pages at a later date should the Examiner desire a copy
89	Samadani et al., "Identification of a Transthyretin Enhancer Site That Selectively Binds the Hepatocyte Nuclear Factor-3 β Isoform," <i>Gene Expression</i> 6:23-33 (1996);
90	Sambrook et al., <i>Molecular Cloning, a Laboratory Manual</i> , Cold Spring Harbor Laboratories, New York (1989) (Title and Copyright Pages Only);

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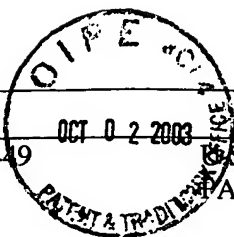
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

91	Samulski et al., "helper-Free Stocks of Recombinant Adeno-Associated Viruses; Normal Intergration Does Not Require Viral Gene Expression," <i>J. Virol.</i> , 63:3822-3828 (1989);
92	Sanberg et al., XXth Int. Congress of the World Fed. Of Hemophilia (1992); Reference could not be obtained at this time. Will provide a copy at a later date should the Examiner desire a copy.
93	Schlehofer et al., "Vaccinia Virus, Herpes Simplex Virus, and Carcinogens Induce DNA Amplification in a Human Cell Line and Support Replication of a Helpervirus Dependent Parvovirus," <i>Virol.</i> 152:110-117 (1986);
94	Shelling and Smith, "Targeted Integration of Transfected and Infected Adeno-Associated Virus Vectors Containing the Neomycin Resistance Gene," <i>Gene Ther.</i> , 1:165-169 (1994);
95	Shigekawa et al., "Electroporation of Eukaryotes and Prokaryotes: A General Approach to the Introduction of Macromolecules into Cells," <i>BioTechn.</i> 6:742-751 (1988);
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97	Thomson et al., "Human Herpesvirus 6 (HHV-6) is a Helper Virus for Adeno-Associated Virus Type 2 (AAV-2) and the AAV-2 rep Gene Homologue in HHV-6 Can Mediate AAV-2 DNA Replication and Regulate Gene Expression," <i>Virol.</i> , 204:304-331 (1994);
98	Tooele et al., "Molecular cloning of a cDNA encoding human antihaemophilic factor," <i>Nature</i> 312:342-347 (1984);
99	Uetsuki et al., "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor – 1 α ," <i>J. Biol. Chem.</i> , 264:5791 (1989);
100	Vehar et al., "Structure of Human factor VIII," <i>Nature</i> 312:337-342 (1984);
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102	Voss, et al., "The role of enhancers in the regulation of cell-type-specific transcriptional control," <i>Trends Biochem. Sci.</i> , 11:287-289 (1986);
103	Wood et al., "Expression of active human factor VIII from recombinant DNA clones," <i>Nature</i> 312:330-337 (1984);
104	Yan et al., "Distinct positive and negative elements control the limited hepatocyte and choroid plexus expression of transthyretin in transgenic mice." <i>EMBO J.</i> 9:869-878 (1990);
105	Yonemura et al., "Efficient production of recombinant human factor VIII by the expression of their heavy and light chains," <i>Prot. Engineer.</i> , 6:669-674 (1993).
106	Young et al., "Adeno-Associated Virus – an Extreme State of viral Defectiveness," <i>Prog. Med. Virol.</i> , 25:113-132 (1979)
107	Zhou et al., "Adeno-Associated Virus 2-Mediated High Efficiency Gene Transfer Into Immature and Mature Subsets of Hematopoietic Progenitor Cells in Human Umbilical Cord Blood," <i>J. Exp. Med.</i> , 179: 1867-1875 (1994)
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APPLICANT – Couto, et al.

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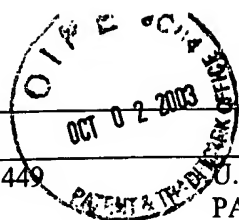
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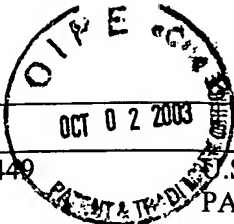
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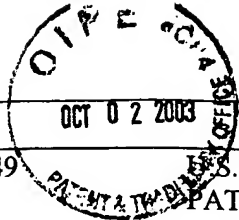
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